510(k) Summary K092469

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

DEC 2 3 2009

Submitter Information

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Contact Person: Allison Scott, RAC

Date: August 7, 2009

Trade Name: O-Scan

Common Name: System, Nuclear Magnetic Resonance Imaging

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

Predicate Device(s)

Tradename	Common name	Class	Product code	Manufacturer	K number
C-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K040877
S-scan	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K080968
AIRIS II	System, nuclear magnetic resonance imaging	II	LNH	HITACHI MEDICAL SYSTEMS	K001334

Device Description

O-scan is a Magnetic Resonance (MR) system, which produces images of the internal structures of the patient's limbs and joints.

The system comprises three main parts:
1. Magnetic unit, containing a permanent magnet
2. Electronic unit
3. Console, comprising a PC, Keyboard, mouse, monitor and operating table.
4. Patient seat
5. Receiving coils

Intended Use(s)

O-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs and joints. It is intended for imaging portions of the arm, including the hand, wrist, forearm and elbow, but excluding the upper arm, and imaging portions of the leg, including the foot, ankle, calf and knee, but excluding the thigh.

O-scan images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in the use of MR equipment, the images can provide diagnostically useful information.

Technological Characteristics

The technological characteristics of the O-Scan are substantially equivalent to those of the predicate devices.

Performance Data

Non-clinical testing of the O-Scan system demonstrated that it met performance requirements and is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Esaote, S.p.A.
% Ms. Allison Scott, RAC
Consultant
The Anson Group, LLC
11460 N. Meridian St., Suite 150
CARMEL IN 46032

DEC 2 3 2009

Re: K092469
Trade/Device Name: O-Scan MR System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: November 17, 2009
Received: November 18, 2009

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092469

Device Name: O-Scan MR System

Indications for Use:

O-scan is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the limbs and joints. It is intended for imaging portions of the arm, including the hand, wrist, forearm and elbow, but excluding the upper arm, and imaging portions of the leg, including the foot, ankle, calf and knee, but excluding the thigh.

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092469